DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Minneapolis District
240 Hennepin Avenue
Minneapolis MN 55401-1999
Telephone: 612-334-4100

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PURGED RTH

July 14, 1998

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Refer to MIN 98 - 42

Alan C. Phillips
President
Altron, Inc.
6700 Industry Avenue NW
Anoka, Minnesota 55303

Dear Mr. Phillips:

We are writing to you because on June 23-25, 1998, an investigator from the Food and Drug Administration (FDA) collected information that revealed a serious regulatory problem involving the feeding pumps that are manufactured at your facility in Anoka, MN.

Under a United States Federal law, the Federal Food, Drug and Cosmetic Act (the Act), these products are considered to be medical devices because they are used to diagnose or treat a medical condition or to affect the structure or function of the body. They are medical devices as defined by Section 201(h) of the Act.

The law requires that manufacturers of medical devices adhere to Quality System Regulations for Medical Devices (QSRs) as specified in Title 21, Code of Federal Regulations, Part 820 (21 CFR 820), in the methods used in, facilities or controls used for manufacturing, packing, storage, or installation of medical devices.

Our inspection found your products violate the law because of:

1. Failure to validate processes to a high degree of assurance and approve them according to established procedures where the results of a process

cannot be fully verified by subsequent inspection and test (21 CFR 820.75, FDA-483 item 1) in that process validations were not performed on critical processes such as the automatic component insertion and for solder used in the wave solder machine;

2. Failure to develop, conduct, control and monitor production processes to ensure that a device conforms to its specifications [21 CFR 820.70(a), FDA-483 item 1] in that the firm has not identified critical processes to be controlled;

3. Failure to establish and maintain procedures for receiving, reviewing and evaluating complaints to ensure that all complaints are processed in a uniform and timely manner and evaluated to determine whether the complaint represents an event which is required to be reported to FDA under Part 803 or 804, Medical Device Reporting [21 CFR 820.198, FDA-483 item 2]. Altron Issue Reports may be used for reporting other issues in addition to complaints, creating a situation whereby complaints may bypass the complaint handling system and are not processed in accordance with that system. The complaint handling system does not address the Medical Device Reporting requirements; and

4. Failure to maintain a Device Master Record (DMR) which includes appropriate production and component specifications [21 CFR 820.181, FDA-483 item 3] in that the DMR does not contain the latest revision of the Device History Record and lacks specifications for the EPROM component.

In legal terms, the products are adulterated under Section 501(h) of the Act.

You should know that this serious violation of the law may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to, seizing your product inventory, obtaining a court injunction against further marketing of the product, or assessing civil money penalties. Also, other Federal agencies are informed about the Warning Letters we issue, such as this one, so that they may consider this information when awarding government contracts.

The specific violations noted in this letter and in the form FDA-483 issued at the close-out of the inspection may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance systems. You are responsible for investigating and determining the causes of the violations identified by the FDA. If the causes are determined to be systems problems you must promptly initiate permanent corrective actions.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. As present, the most responsible individual at Altron, Inc., it is ultimately your responsibility to ensure that devices manufactured at your facility in Anoka, MN, are in compliance with each requirement of the Act and regulations.

It is necessary for you to take action on this matter now. Please let this office know in writing within 15 working days from the date you received this letter what steps you are taking to correct the problem. We also ask that you explain how you plan to prevent this from happening again. If you need more time let us know why and when you expect to complete your correction. Please direct your response to Compliance Officer Howard Manresa at the address indicated on the letterhead.

Finally, you should understand that there are many FDA requirements pertaining to the manufacture and marketing of medical devices. This letter pertains only to the issue of QSRs for your devices and does not necessarily address other obligations you have under the law. You may obtain general information about all of FDA's requirements for manufacturers of medical devices by contacting our Division of Small Manufacturers Assistance at 1-800-638-2041 or through the Internet at http://www.fda.gov.

If you have more specific questions about how FDA marketing requirements affect your particular device or about the content of this letter please feel free to contact Mr. Manresa at (612) 334-4100 ext. 156.

Sincerely,

James A. Rahto
Director
Minneapolis District

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Enclosure: FDA-483, 6/25/98